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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,444

06/02/2006

Matthias Witschel

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03/05/2009

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WASHINGTON, DC 20005

EXAMINER

BIANCHI, KRISTIN A

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

03/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/581,444	Applicant(s) WITSCHER ET AL.	
	Examiner KRISTIN BIANCHI	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 11, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 15 is/are rejected.
- 7) ☒ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/02/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 and 13-15 are pending in the instant application. Claims 6-8, 11, 13, and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected subject matter. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference which anticipates one group would not render obvious the other. Claims 1-5 and 15 are rejected. Claims 9 and 10 are objected.

Information Disclosure Statement

The information disclosure statement filed on June 2, 2006 was considered and a signed copy of form 1449 is enclosed herewith.

Election/Restrictions

Applicant's election with traverse of Group I and Compound 3.6 in the response filed on December 3, 2008 is acknowledged. The traversal is on the grounds: that the restriction is improper under the PCT Rules because the chemical structures of the intermediates and the final product are technically closely interrelated. Applicant also argues that the Examiner has advanced no reasons why restriction should be required among Groups II, IV and I. These arguments are not found to be persuasive. As stated in the restriction requirement filed on November 4, 2008, Groups I and III consist of compounds of different formulas which do not have a common core structure within the chemical structure of each compound, therefore, there is not a special technical feature present which links the claims. Also, the search for the products (i.e. compounds of

Art Unit: 1626

formula I versus compounds of formula III), the process of making the products and the process of using the products are not coextensive. Separate searches would be required to determine the totality of the prior art that may exist that anticipates and/or makes obvious the different Groups (i.e. I-IV). Therefore, the restriction requirement is still deemed proper and is maintained.

However, upon further consideration, the requirement to elect a species has been withdrawn (i.e. Group I, claims 1-5, 9, 10, and 15, have been searched and examined in their entirety).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

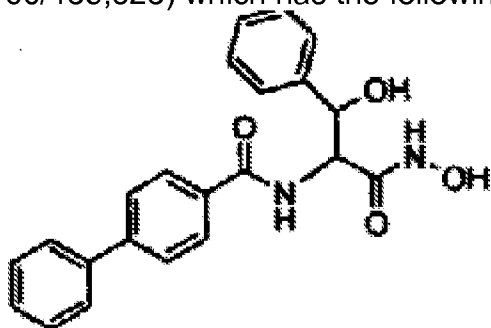
Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0229955 (Andersen et al.), which has a provisional application No. 60/438,523, filed on January 8, 2003. The filing date of the provisional application can

Art Unit: 1626

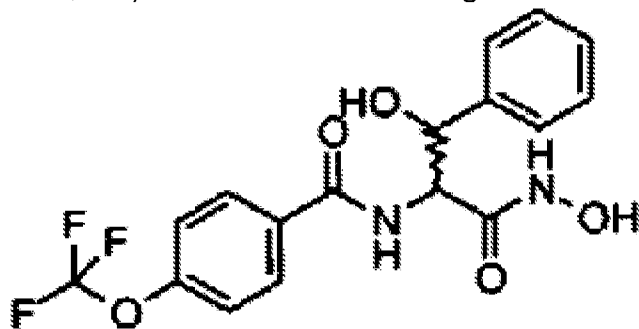
be used as the 102(e) date under 119(e) because the provisional application properly supports the subject matter relied upon to make the rejection. See MPEP § 706.02(f)(1).

Determining the scope and contents of the prior art

Andersen et al. discloses compounds which are used for treating bacterial infections, such as the compound of Example 267 (Table 1-continued on page 164 in US 2004/0229955) or Example 374 (page 123 in provisional application No. 60/438,523) which has the following structure



Also disclosed in Andersen et al. is the compound of Example 1307 (page 486 in US 2004/0229955) or Example 594 (page 145 in provisional application No. 60/438,523) which has the following structure



Ascertaining the differences between the prior art and the claims at issue

The only differences between the compound of Example 267 (in US 2004/0229955) and a compound of the instant claims is that the compound of Example 267 has a phenyl for R3 and hydrogen for R1 and R8.

The only differences between the compound of Example 1307 (in US 2004/0229955) and a compound of the instant claims is that the compound of Example 1307 has hydrogen for R1 and R8.

Establishing a prima case of obviousness

To those skilled in the chemical art, one homologue is not an advance over an adjacent member of a homologous series. The reason for this is that one of

Art Unit: 1626

ordinary skill, knowing the properties of one member of a series, would know what properties to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963).

Also, positional isomers are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. MPEP §2144.09, *Ex parte Henkel* 130 USPQ 474. *Ex parte Weston*, 121 USPQ 429.

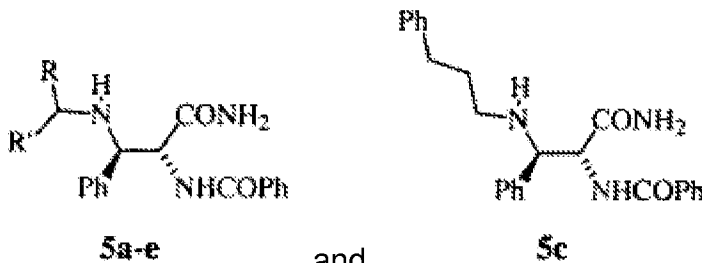
Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the compounds disclosed in Andersen et al. and make the modifications necessary (i.e. to move the phenyl in the compound of Example 267 to the R1 position and to replace the hydrogen of R8 with methyl and to replace the hydrogen atoms of R1 and R8 of the compound of Example 1307 with methyl groups) to arrive at compounds of the instant invention with a reasonable expectation of success for obtaining compounds with the same activity. The motivation would have been to make additional compounds which can be used to treat bacterial infections.

Thus, a *prima facie* case of obviousness has been established.

Claims 1-4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zupancic et al. (*J. Heterocyclic Chem.*, **36**, 607 (1999)).

Determining the scope and contents of the prior art

Zupancic et al. discloses compounds which are non-proteinogenic amino acids, which have importance in medicinal and biotechnological fields, such as



(page 607).

Ascertaining the differences between the prior art and the claims at issue

The only differences between the compounds disclosed in Zupancic et al. and compounds of the instant claims is that the compounds disclosed in Zupancic et al. have hydrogen atoms for R1 and R8.

Establishing a prima case of obviousness

It is known in the art that bioisosteres are substituents or groups with similar physical or chemical properties that impart similar biological properties to a chemical compound. In drug design, the purpose of exchanging one bioisostere for another is to enhance the desired biological or physical properties of a compound without making significant changes in chemical structure. The substitution of hydrogen by fluorine is one of the more common employed monovalent isosteric replacements (Chemical Reviews, 1996, Vol. 96, No. 8, page 3149, 1. Fluorine vs Hydrogen Replacements).

To those skilled in the chemical art, one homologue is not an advance over an adjacent member of a homologous series. The reason for this is that one of ordinary skill, knowing the properties of one member of a series, would know what properties to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963).

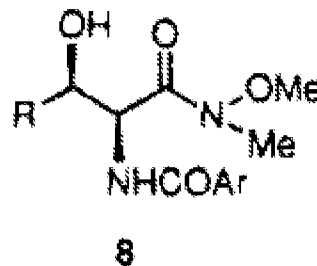
Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the compounds disclosed in Zupancic et al. and make the modifications necessary (i.e. to replace the hydrogen atom of R1 with fluorine and to replace the hydrogen atom of R8 with methyl) to arrive at compounds of the instant invention with a reasonable expectation of success for obtaining compounds with the same activity. The motivation would have been to make additional non-proteinogenic amino acids.

Thus, a *prima facie* case of obviousness has been established.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawamura et al. (*J. Org. Chem.* **1995**, 60, 1727-1732).

Determining the scope and contents of the prior art

Sawamura et al. discloses optically active α -amino aldehydes and ketones which are of great interest as chiral building blocks for the synthesis of polyfunctional



unusual amino acids, etc., such as the compound **8a**:
wherein R is phenyl and Ar is 3,5-(NO₂)₂-C₆H₃ (page 1728).

Art Unit: 1626

Ascertaining the differences between the prior art and the claims at issue

The only difference between the compound disclosed in Sawamura et al. and a compound of the instant claims is that the compound disclosed in Sawamura et al. has hydrogen for R1.

Establishing a prima case of obviousness

Positional isomers are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties.

MPEP §2144.09, *Ex parte Henkel* 130 USPQ 474. *Ex parte Weston*, 121 USPQ 429.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the compound disclosed in Sawamura et al. and make the modification necessary (i.e. to move the NO₂ of R2 to R1) to arrive at a compound of the instant invention with a reasonable expectation of success for obtaining a compound with the same activity. The motivation would have been to make additional optically active α -amino aldehydes and ketones.

Thus, a *prima facie* case of obviousness has been established.

Claim Objections

Claims 9 and 10 are objected for depending on a previously rejected base claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/
Primary Examiner, Art Unit 1626

Kristin Bianchi
Examiner
Art Unit 1626
